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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,833	04/27/2001	James J. Barry	12013/58401	8482

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KENYON & KENYON LLP
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER	
STEWART, ALVIN J	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/842,833	BARRY ET AL.	
	Examiner	Art Unit	
	Alvin J. Stewart	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed November 30, 2006 have been fully considered but they are not persuasive.

The Applicant's representative discloses that none of the cited references disclose or suggest a "releasable implant releasably positioned in physical communication with the first implant adhesion-resistant treatment on the surface of said releasable implant retention region" as recited in claim 1. Also, the Applicant's representative discloses that in the Michal reference the embodiments have either a coating on the stent or in the catheter, but not both.

The examiner agrees partially with the Applicant's arguments. For the above reasons, the Examiner is using the Hossainy reference as a secondary reference because the Michal reference does not discloses all the structure limitations of independent claim 1. The examiner wants to show that it is well known in the art the use of a catheter having an adhesion-resistant treatment in combination with a stent in order to treat a specific blood vessel site and promote the quick release of the stent from the delivery system. In addition, the Examiner wants to show that it is well known in the art to use a stent with a coated drug in order to treat a condition in a blood vessel. Therefore, it would have been obvious to one having ordinary skill in the art to add an additional coating (for example, a drug coating) around the Michal reference stent in order to have a quick release from the delivery system and at the same time treat a condition within the blood vessel for a period of time with a drug coat around a stent (Hossainy). For the above reasons, the Examiner believes that the rejection is still proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 6, 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al US Patent 6,287,285 B1 in view of Hossainy et al US Patent 6,153,252.

Michal et al discloses a coated implant delivery system comprising an implant delivery device (10) with a first end (22), a second end (11), an inner lumen (see Fig. 8) and a stent (30). The first end has a releasable implant retention region (13), the region has an accessible surface (surface of the balloon), the accessible surface has a first implant adhesion-resistant coating (20) (see col. 7, lines 3-6; col. 7, lines 28-48) and the stent has a first implant coating (19) (see col. 10, lines 14-37). The two coatings are in physical communication with the stent and the accessible surface and the first implant coating face the releasable implant retention region.

Stent (30) discloses a coating (18) made of two layers (19 & 20) (see Fig. 12 and col. 12, lines 23-27). The Examiner interpreted layer (20) of the stent (30) as being part of the retention region (13) because the layer (20) is in physical contact with the wall of the balloon (13). The Examiner interpreted layer (19) as being part of the stent because is in physical contact with the stent wall.

Regarding claims 6 and 7, see col. 1, lines 15-35).

Regarding claim 11, see col. 12, lines 14-17.

However, Michal does not disclose a stent having a first implant coating.

Hossainy et al teaches a stent having a plurality of coatings for the purpose of delivering therapeutic and pharmaceutical agents to a targeted area.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stent of the Michal et al reference to add a plurality of coatings around the stent in order to deliver therapeutic and pharmaceutical agents to a targeted area.

Claims 4, 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al US Patent 6,287,285 B1 in view of Hossainy et al US Patent 6,153,252 and in further view of Sydney et al US Patent 6,306,144 B1.

Michal et al as modify by Hossainy et al disclose the invention substantially as claimed. Additionally, Michal et al discloses two coaxial sleeves positioned in physical communication with the retention region. The Examiner interpreted the two coating (19 & 20) as being the two coaxial sleeves. The two coatings run along the length of the stent, therefore, the two coatings are coaxial to the axis of the stent and have an open mesh sleeve configuration. However, Michal et al as modify by Hossainy et al do not disclose an exterior of the second end of the implant delivery device treated with a second adhesion-resistant coating, a second adhesion-resistant coating on the accessible surface and a non-adhesive coating made of hydrogel.

Sydney et al teaches a stent delivery system having an implant delivery device (10), an elongated member (22), an inflatable member (18) and a stent (17). The elongated member (22) has a first end and a second end. The first end has a first coating and the second member has a second coating (see col. 2, lines 41-56 and col. 3, lines 16-19). The balloon comprises three different areas (32, 30 & 36) coated with two different lubricants (see col. 4, lines 52-62) for the

purpose of avoiding unexpected movement of the stent when it is installed within the human body.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the type of lubricants of the Michal et al reference with the different lubricants and the different coating location at the catheter of the Sydney et al reference in order to avoid unexpected movements of the stent during the installation.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al US Patent 6,287,285 B1 in view of Hossainy et al US Patent 6,153,252 and in further view of Sahatjian et al US Patent 6,409,716 B1.

Michal et al as modify by Hossainy et al disclose the invention substantially as claimed. However, Michal et al as modify by Hossainy et ado not disclose a coating made of carbowax.

Sahatjian et al teaches a delivery system comprising an expandable balloon (4) and a stent (50). Additionally, Sahatjian discloses a coating soluble in water (e.g. carbowax) for the purpose of having a smooth delivery through the blood vessel (col. 3, lines 57-63).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coating of the Michal et al reference with the carbowax coating of the Sahatjian et al in order to have a smooth delivery through the blood vessel (col. 3, lines 57-63).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al US Patent 6,287,285 B1 in view of Hossainy et al US Patent 6,153,252 and in further view of Brown US Patent 6,348,060 B1.

Michal et al as modify by Hossainy et al disclose the invention substantially as claimed. However, Michal et al as modify by Hossainy et al do not disclose a coating made of polymethacrylic (PEO).

Brown teaches a delivery system (10) comprising an expandable balloon (14) and a stent (18). Additionally, Brown discloses a coating made of PEO for the purpose of allowing a low profile on deflation of the balloon (see col. 4, lines 20-37).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coating of the Michal et al reference with the PEO coating of the Brown in order to allow a low profile on deflation of the balloon (see col. 4, lines 20-37).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Stewart

ALVIN J. STEWART
PRIMARY EXAMINER
Art Unit: 3738

March 5, 2006.